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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,681	02/23/2005	Henning Walczak	18744-0030	9513

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EXAMINER	
SCHUBERG, LAURA J	

ART UNIT	PAPER NUMBER
1657	

MAIL DATE	DELIVERY MODE
08/11/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/525,681	WALCZAK ET AL.	
	Examiner	Art Unit	
	LAURA SCHUBERG	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is responsive to papers filed 05/15/2008.

Claims 1-15 are currently pending; claims 1-4 have been amended, no claims have been added or canceled.

Claim 15 was withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 10/15/2007.

Claims 1-14 have been examined on the merits.

Previous Rejections

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Response to Arguments

Applicant's arguments filed 05/15/2008 have been fully considered but they are not persuasive.

Applicant argues that the Alnemri reference does not anticipate the claims as amended. Applicant asserts that there is no literal or inherent teaching by Alnemri that a disease associated process such as activation of cytokinsecretion, induction of direct cell-bound signals, or transmission of signals regulating proliferation, differentiation, and/or senescence can be monitored and modulated by determining and influencing the amount or activity of caspase-10 or caspase-10 isoforms.

This is not found persuasive because the Alnemri reference teaches the same physical steps as the claimed method which are "determining and influencing the amount or activity of caspase-10 or caspapse-10 isoforms". Wherein the activatory process comprises transmission of signals regulating proliferation, differentiation and/or senescence is an inherent component to the relationship of capspase-10 and diseases such hyperproliferative, inflammatory and auto-immune diseases.

Applicant argues that simply because there may be some general overlap in the diseases listed in Alnemri and that within the present application, this is insufficient to then assume Alnemri inherently anticipates the presently claimed invention by assuming all diseases listed in Alnemri inherently are triggered by non-apoptosis signals emanating from death receptors or non-apoptosis signals emanating from non-death receptors of the TNF receptor family.

This is not found persuasive because it is not assumed that all diseases listed in Alnemri are inherently triggered by non-apoptosis signals emanating from death receptors or non-apoptosis signals emanating from non-death receptors of the TNF receptor family, only those that are specifically mentioned as doing so in Applicant's

specification (pages 5-6) such as ovarian carcinoma, breast carcinoma, prostrate carcinoma, etc.. If Applicant's invention requires that the non-apoptosis signaling be established regardless of the disease being treated then this would require that the claimed invention include such a step as an essential element.

Therefore, the claims remain rejected as cited below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Alnemri et al (US 5,786,173- from IDS).

Amended claim 1 is drawn to a method of monitoring or modulating a disease-associated activatory process, wherein the activity process comprises activation of cytokinsecretion, induction of direct cell-bound signals, or transmissions of signals regulating proliferation, differentiation, and/or senescence, the method comprising determining or influencing the amount or activity of caspase-10 or caspase-10 isoforms in a cell or an organism, wherein the activatory process is triggered by non-apoptosis

signals emanating from death receptors or non-apoptosis signals from non-death receptors of the TNF receptor family.

Dependent claims include the type of triggering of the activatory processes, the type of diseases included, type of information monitored, level of determination and level of monitoring.

Alnemri et al disclose methods of monitoring and modulating disease-associated activatory processes comprising determining and/or influencing the amount or activity of Mch4 (which is the caspase 10a isoform) in a cell or organism at the nucleic acid and protein level (column 8 line 22-column 12 line 37) (claims 1, 9-14). Although it is not further specified that non-apoptosis signals are meant (and only apoptosis is discussed), cancer and autoimmune diseases are included for treatment and monitoring (column 8), and these types of diseases fall under the group of activatory processes that are also triggered by non-apoptosis signals, according to the present application (pages 5-6) and inherently include the death receptors and non-death receptors claimed by Applicant as well as receptor crosslinking (claims 2-5, 7, 8). The inclusion of systemic lupus erythematosus (column 8 line 30), while characterized as an autoimmune disease, can also be characterized as a skin inflammatory disease since it inherently includes symptoms of skin lesions as well as other inflammatory related symptoms (claim 6).

Inherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art. However, the discovery of a previously unappreciated

property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition or method patentably new to the discoverer. The public remains free to make, use, or sell prior art compositions or processes, regardless of whether or not they understand their complete makeup or the underlying scientific principles which allow them to operate. The doctrine of anticipation by inherency, among other doctrines, enforces that basic principle.

Thus, a reference may be anticipatory if it discloses every limitation of the claimed invention either explicitly or inherently. A reference includes an inherent characteristic if that characteristic is the natural result flowing from the reference's explicitly explicated limitations.

Therefore the teachings of Alnemri et al anticipate Applicant's invention as claimed.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA SCHUBERG whose telephone number is (571)272-3347. The examiner can normally be reached on Mon-Fri 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford/
Primary Examiner, Art Unit 1651

Laura Schuberg